## PATENT COOPERATION TREATY

# **PCT**

# TRANSLATION INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 200412F-0422	FOR FURTHER ACTION	See Form PCT/IPEA/416					
International application No.	International filing date (day/mo	nth/year) Priority date (day/month/year)					
PCT/JP2004/019437	24.12.2004	26.12.2003					
International Patent Classification (IPC) or na	tional classification and IPC	I					
A61K31/365, A23L1/30, A61P35/00, C07D307/33							
Applicant Tokyo University of Agriculture and Technology TLO Co., Ltd.							
This report is the international prel- under Article 35 and transmitted to t		shed by this International Preliminary Examining Authority					
2. This REPORT consists of a total of	<b>5</b> sl	neets, including this cover sheet.					
3. This report is also accompanied by A	ANNEXES, comprising:						
a. (sent to the applicant an	d to the International Bureau) a tota	al of <b>4</b> sheets, as follows:					
sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).							
sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental							
Box.							
b. (sent to the International	Bureau only) a total of (indicate ty	pe and number of electronic carrier(s))					
related thereto, in compute	er readable form only as indicated	, containing a sequence listing and/or tables in the Supplemental Box Relating to Sequence Listing (see					
Section 802 of the Adminis	•	in the Supplemental Box Relating to Sequence Disting (see					
4. This report contains indications relat	ting to the following items:						
Box No. I Basis of th	e report						
Box No. II Priority							
Box No. III Non-estable	ishment of opinion with regard to r	ovelty, inventive step and industrial applicability					
Box No. IV Lack of un	ity of invention						
BON 110. 1							
Box No. VI Certain do	Jo. VI Certain documents cited						
Box No. VII Certain de	fects in the international application						
Box No. VIII Certain ob	Box No. VIII Certain observations on the international application						
Date of submission of the demand	Date of co	mpletion of this report					
		*					
Name and mailing address of the IPEA/JP		Authorized officer					
Facsimile No.		No.					

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/019437

Box	No. I	I Basis of the report					
1.		th regard to the language, this report is based on the internation icated under this item.	al application in the language in	which it was filed, unless otherwise			
		This report is based on translations from the original language which is the language of a translation furnished for the purposition of the international application (Rule 12.4) publication of the international application (Rule 12.4) international preliminary examination (Rule 55.2 and/or	or 55.3)	·			
2.	rece	th regard to the <b>elements</b> of the international application, this reviving Office in response to an invitation under Article 14 are report):  the international application as originally filed/furnished the description:  pages 1,4–19	referred to in this report as "on				
		pages* 2-3,3/1	received by this Authority on	26.10.2005			
		pages*					
	$\boxtimes$	the claims:					
		nos.		as originally filed/furnished			
		nos.**					
		nos.* 1-5					
		nos.*					
	$\boxtimes$	the drawings:					
		sheets 1/5-5/5		as originally filed/furnished			
		sheets*					
		sheets*					
	П	a sequence listing and/or any related table(s) – see Suppleme					
	$\exists$		intal Box Relating to Sequence En	isting.			
3.	ш	The amendments have resulted in the cancellation of:					
			the claims, nos.				
			the drawings, sheets/figs				
4							
4.	Ш	This report has been established as if (some of) the amenda they have been considered to go beyond the disclosure as file					
		the description, pages					
		the claims, nos.					
		the drawings, sheets/figs					
		the sequence listing (specify):					
		any table(s) related to sequence listing (specify):					
*	If ite	em 4 applies, some or all of those sheets may be marked "supe	rseded."				

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box			ticle 35(2) with regard to novelty, inventive step or industrial applicability; porting such statement	
1.	Statement			
	Novelty (N)	Claims	1-3	YES
		Claims	4-5	NO
	Inventive step (IS)	Claims		YES
		Claims	1-5	NO
	Industrial applicability (IA)	Claims	1-5	YES
		Claims		NO

- 2. Citations and explanations (Rule 70.7)
  - Document 1: US 2003-0118676 A (Council of Scientific and Industrial Research), 26 June 2003
  - Document 2: JP 11-221048 A (Archer Daniels Midland Co.),
    17 August 1999
  - Document 3: JP 2003-63971 A (Tama Biochemical Co., Ltd.), 5 March 2003
  - Document 4: JP 2002-541158 A (Hormos Nutraceutical OY Ltd.), 3 December 2002
  - Document 5: Phytochemicals in Human Health Protection,

    Nutrition and Plant Defense, 1999, pages 51

    to 65
  - Document 6: JP 1-228928 A (Tsumura & Co.), 12 September 1989
  - [1] The invention set forth in claims 4 and 5 lacks novelty in the light of documents 2 to 5 cited in the international search report.

Document 2 (claims 18, 61 and 62) sets forth a food containing enterolactone.

Document 3 (paragraphs [0016] and [0019]) sets forth a food containing a lignan precursor of enterolactone.

Document 4 (claims 1 and 10; paragraph [0009]) sets forth a functional food containing a lignan precursor of

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

enterolactone.

Document 5 (table 1) sets forth a food containing enterolactone.

In contrast, the food of the invention set forth in claims 4 and 5 is used "for improving fat metabolism abnormalities", and although this feature is not disclosed in documents 2 to 5, in the technical field of food, this food cannot be distinguished, even if the food is specified by functional properties.

[2] The invention set forth in claims 1 to 3 does not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 (tables 1 and 3) indicates that matairesinol which is a lignan precursor of enterolactone has an activity of suppressing the proliferation of hepatoma, therefore a person skilled in the art would be able to verify the activity of suppressing the proliferation of hepatoma of different types of lignan precursors similar to matairesinol as necessary.

Moreover, although document 1 does not set forth the apoptosis inducing activity, cell cycle stoppage activity and fat metabolism abnormality improving activity of said precursor, the applicable disorder for the composition set forth in claims 1 to 3 of this application is hepatoma, therefore the effect of the invention of this application is not particularly marked.

[3] The invention set forth in claims 1 to 5 does not involve an inventive step in the light of document 6 cited in the international search report.

Document 6 (claim 7) indicates that enterolactone

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

has anti-cancer activity, therefore a person skilled in the art would be able to attempt to use said lactone in the treatment of hepatoma, which is a specific cancer, as necessary.

In addition, a person skilled in the art would be able to add the enterolactone set forth in document 6 to a food as necessary.

[4] The invention set forth in claims 1 and 2 does not involve an inventive step in the light of documents 2 to 5 cited in the international search report.

Documents 2 to 5 indicate that enterolactone or a lignan derivative of said lactone has anti-cancer activity, therefore a person skilled in the art could attempt to apply these compounds to the treatment of hepatoma, which is a specific cancer, as necessary.